



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of) Confirmation No.: **7183**
ARTLEY et al.) Examiner: **Boyd, Jennifer A.**
Serial No.: **10/022,959**) Art Unit **1771**
Filed: **December 18, 2001**) Docket No.: **T117 9001**
For: **POLYETHYLENE GLYCOL SATURATED SUBSTRATE AND**
METHOD OF MAKING

DECLARATION UNDER 37 C.F.R. 1.132

I, John W. Artley, of 4 Park Avenue, Apt. 10-R, New York, NY 10016, state the following as true:

1. I am one of the co-inventors of the claimed subject matter in the above-referenced application.

2. The present application relates to a method of manufacturing a polyethylene glycol treated fabric. The method includes exposing a fabric to a polyethylene glycol formulation having both an acid catalysis and a resin. The treated fabric is then heated and cured to initiate a catalytic reaction for bonding the polyethylene glycol formulation to the fabric. The bonded fabric is then washed or neutralized to a pH of between about 6.5 and about 7.5 and then dried. The neutralization step is critical given that an acid catalyst is used to initiate the PEG reaction and any remaining acid residue hydrolyzes causing a reversal of the PEG reaction.

3. I am the licensee of the three Vigo/Bruno patents (the "Patents," or "Technology") and the corresponding technology. I was granted the license from the United States Department of Commerce where both Dr. Vigo and Joe Bruno were employees of the United States Department of Agriculture Southern Regional Research Center. The licensed Vigo technology is equivalent to that taught in the cited Vigo articles.

I began development of my first product incorporating the licensed technology as directed by the teachings of Vigo and Bruno. The product was a durable underpad for incontinence patients that, when treated with the licensed Vigo/Bruno Technology, would offer significant competitive advantages when compared to underpad products currently available from other manufacturers. The improved features included better moisture absorption and management, better patient comfort, improved odor control, longer product life, and an improved physical appearance over the useful life of the product. A business plan for this healthcare product was also written.

Vigo Protocol

We followed the Vigo protocol, including the washing and rinsing of the treated fabrics with a detergent as taught in the Vigo articles, in our first trials. Our first trials were conducted in East Providence, Rhode Island at a nonwoven airlaid production facility owned by the Allied Signal Company. Allied Signal used the two airlaid production lines there to manufacture nonwoven media for their automotive, and truck, filters.

With the exception of a saturation tank and rollers used to apply the formula to the substrate, and a shallow sheet metal tank specially fabricated for rinsing the treated airlaid media in a mild detergent after application and curing of the formulation (a step outlined in the Vigo/Bruno patents), the two airlaid production lines remained in a stock condition.

The plan was to initially produce several hundred running yards of the airlaid media treated with the technology, and have the resulting fabric converted into prototype

underpads for testing at several healthcare facilities (both extended care and hospital) in Lancaster County, Pennsylvania.

The treated roll goods were to be trucked by motor freight to Brooklyn, New York for quilt stitching. From there the fabric was to be shipped to a cutting and sewing operation in Pennsylvania for converting into finished prototype underpads.

For this very first trial (at Allied Signal) from bales of polyester fibers we first produced the airlaid media. The rolls of finished airlaid media were then moved to the second line for application of the formulation as embodied in the patents. This was followed by the curing of the treated substrate in an approximate sixty-foot oven, and the subsequent washing of the treated fabric in the specially fabricated tank.

Although for this first trial the treated, cured, and washed substrate had a somewhat "boardlike" stiff hand, and a slightly "oily" feel to it, we nevertheless decided to continue on with converting the treated fabric into prototype incontinence products.

Pooling of the PEG

By motor freight the treated goods arrived in Brooklyn for quilt stitching. The following morning I received a telephone call from the owner of the quilt stitching operation saying there was something wrong with the rolls of material he had just received. The owner said that a liquid was draining from the rolls and pooling in the bottom of the plastic wrapping material.

I took a taxi to Brooklyn and observed that the plastic wrapping contained unknown amounts of a thick, pale yellow fluid. This fluid had the general appearance and consistency of the polyethylene glycol (PEG) used in the formulation.

Various phone calls were made to Allied Signal and to Vigo, but nobody had an answer to why the PEG and other components of the formulation had seemingly debonded from the nonwoven substrate.

Subsequently, additional trials were run at Allied Signal. In an attempt to solve the problem, on an *ad hoc* basis, the loft of the airlaid media substrate was changed, oven temperatures were adjusted, high pressure water nozzles were added to the washing tank, oven dwell times were tinkered with, and other variables available to us were adjusted.

With these trials, over time, slight improvements were noted particularly in getting the formulation to remain on/in the fabric long enough for a significant number of prototype products to be made up in Pennsylvania in preparation for actual user trials. Each prototype pad was composed of a top cover quilt stitched to the absorbent middle layer incorporating the technology. To these two layers was attached a waterproof backing material, with all three layers (each 32" x 36") joined by sewing together around the periphery.

Washout of the PEG

Prior to commencement of the initial user trials, it was decided to conduct washability tests on the finished prototype underpads incorporating the licensed technology. The goal was a hundred wash/drying cycles (a loose industry standard) before the underpad is thrown away as no longer being useable. Without meeting this standard, an incontinence product would not be a commercially viable product.

Approximately a hundred of the prototype underpads were taken to a special facility in York, Pennsylvania where blue jeans were stone washed in large commercial washer/dryer units for various manufacturers. The prototype pads (with an average cured dry weight determined first, becoming the "standard") were placed in several of the commercial laundry devices, and washed, and dried. As part of the testing process, after each wash/dry cycle, a sampling of the pads would be reweighed and compared against the previously determined standard. Even after the first wash/dry cycle, it was observed that the weight loss was significant. Perhaps by as much as twenty-percent. And so it was with each of the following wash/dry cycles until after a few more cycles the prototype pads weighed approximately the same as a pad *not treated* with the licensed technology. In other words, there had been virtually a 100% washout of the formulation from the treated pads.

Again, further telephone calls were made to all involved in the development of the technology as well as the technicians at Allied Signal. All protocols were double checked, and suppliers contacted. But once more, nobody had an answer to the washout problem.

Around this time Allied Signal began moving their airlaid media production operation to the Midwest and I lost the availability of the East Providence nonwoven production lines.

I then began working with a large textile operation in North Carolina who had taken an interest in the possible potential of the licensed technology with a view of incorporating treated products into their existing product lines. Operating under Confidentiality and Nondisclosure Agreements, with this relationship I was now able to bring expanded facilities, a larger manufacturing/technical team, and an in place distribution network, to the technology commercialization project.

Discovery of the Solution to Washout and Pooling

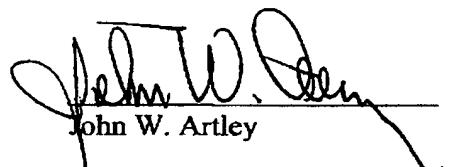
Over a period of many months, and after the treating of literally thousand of running yards of various types of materials with the Technology, I and my co-inventor slowly were able to discover the solutions to the washout problem.

We discovered the criticality of the oven curing temperatures, and oven dwell times, and the neutralization of the residual acidity of a treated substrate. We discovered that if after the application of the licensed technology, and its subsequent curing, if the treated substrate was not quickly neutralized to a pH between about 6.5 to about 7.5, the residual acid content of the formulation still held within the treated substrate would negatively react with the crosslinking (bonding) of the polyethylene glycol to the fabric. This acidic reaction would cause the formula to *debond* from the fabric, with the formula reverting to its viscous, and/or liquid state. Once this had occurred, the remnants of the formula would simply leach from the previously treated fabric.

After discovering that the hydrolyzed acidic residue residing in the treated PEG fabric resulted in the reversal of the PEG reaction, we then discovered that treating the fabric with a strong basic solution neutralized the finished fabric such that the acid residue was removed. Thus, the debonding of the formulation was eliminated, the hand of the treated fabrics further improved, and, subsequently, the licensed technology was successfully and cost effectively applied to numerous fabrics and textile products with outstanding results. As an example, durable nonwoven underpads treated with the

Technology after making changes to the process, successfully passed 125 wash/dry test cycles before being pulled from further testing.

I hereby declare that all statements made herein are made of my own knowledge and are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the application or any patent issued there from.



John W. Artley
Apr. 11 22, 2006
Date